

REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1-2, 5-8, 11-12, 17-21 and 24-30 are pending in this application. No claims are amended, added or cancelled. Claims 1, 17, 24 and 29 are the independent claims.

Rejections under 35 U.S.C. § 102

Little

Claims 29-30 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Little et al. (hereinafter "Little"), U.S. Patent No. 5,858,974. Applicants respectfully traverse this rejection for the reasons detailed below.

The Office Action stated that the claims are directed to a method of modulating immunological activities comprising orally administering fungal immunomodulatory protein or protein fused with FIP to a subject, Little discloses peptides of human bactericidal/permeability-increasing protein (BPI) from about position 148 to about position 161 of SEQ ID NO: 251 which have antifungal activity (See claim 1). Little allegedly further discloses treating fungal infections by administering the peptide orally to a subject (See claim 14) and that the peptide can be synthesized or recombinantly produced (See detailed paragraph 13). Applicants respectfully disagree and submit that Little does not teach or suggest all of the limitations of claim 29.

In Little, the Bactericidal/Permeability-Increasing Protein (BPI) has antifungal activity, which acts as an antibiotic, while the main function for the

fungal immunomodulatory protein (FIP) of claim 29 is facilitating and improving the immune system, and strengthening the immunocyte. As BPI and FIP are totally different proteins, and their mechanisms against pathogens are also not the same, Applicants submit that Little does not teach or suggest the fungal immunomodulatory protein as recited in claim 29.

In addition, although oral intake can be applied to BPI or FIP, page 5 of the specification states “[s]ince FIP can be absorbed in the digestion system by fusing FIP with other proteins, FIP can be used as a delivery system to carry other proteins into the target organism and orally administering the fusion protein should supply benefits of both genes composite of the fusion gene to the target organism.”

As stated in the specification as filed on page 5, last paragraph, the oral intake of a fused protein is not merely delivery of a protein into the body, but also establishes a new drug delivery system. The BPI mentioned in Little is only used to treat fungal infections, while FIP may be taken individually or fused with another protein, which means other proteins or drugs can be delivered with FIP to body. Moreover, intact yeasts comprising the FIP can be orally administered to and absorbed by the target organism without purifying the protein from the host, thereby reducing the cost of utilization.

Because of the superior bio-safety of yeast, the purifying process will be no longer necessary when producing FIP drugs, and costs will be reduced. As such, Applicants submit that one of skill in the art would not know the specific peptide sequences that could be integrated into yeast, e.g., *Saccharomyces cerevisiae*, and therefore, undue experimentation would be required. Therefore,

Applicants submit that Little does not teach or suggest orally administering fungal immunomodulatory protein or protein fused with FIP to a subject as recited in claim 29.

The Applicants, therefore, respectfully request that the rejection to Claims 29-30 under 35 U.S.C. § 102(b) be withdrawn.

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

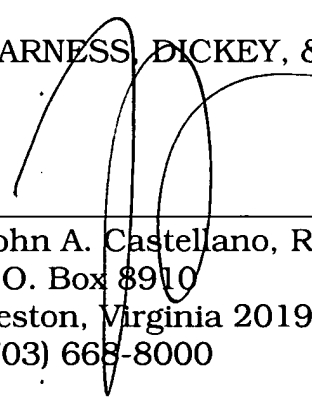
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By



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